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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,532	05/25/2001	Beverly L. Davidson	9431-16065	4232

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/866,532	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-3,5-7,11-14 and 19-21*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejections of Claims 19 and 20 under 35 U.S.C. 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because:

Evidence traversing rejections is not considered timely when submitted after a final rejection, unless submitted in response to a new ground of rejection made in the final rejection. In this case, no new ground of rejection was made in the final rejection. See MPEP 716.01. Therefore, the various references submitted after final have not been considered. Likewise, Applicants' arguments relying upon the references submitted after final will not be considered.

Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted prior to a final rejection or after final rejection and submitted with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection. See MPEP 716.01.

The reference of Brooks et al. (2002, PNAS 99: 6216-6221) has already been considered and is not deemed to evidence enablement of the claimed invention, which is directed to transducing **cerebellar** neurons, not cells of the striatum, cerebral cortex, and hippocampus, as described by Brooks et al. Brooks et al. does not teach treating central nervous system (CNS) disorders by transducing cerebellar neurons. The instant specification does not provide specific guidance for expressing β-glucuronidase at therapeutic levels in the striatum, cerebral cortex, or hippocampus as described by Brooks et al. Since this reference is post-filing art, one of skill in the art would not have had the benefit of the teachings of Brooks et al. (2002) and therefore would not have been able to develop a therapeutic protocol for the treatment of lysosomal storage disease without undue experimentation. The limited teachings of the specification would not have led one of skill in the art to develop the protocol described by Brooks et al. Rather the

instant method is directed to providing therapeutic expression within **cerebellar** neurons. Thus, Applicants' arguments are not commensurate in scope with the scope of the claims. Applicants argue that the methods of Brooks et al. are analogous to the methods taught in the instant specification and therefore "provides credible evidence that gene delivery methods as described in the present application can provide a therapeutic benefit and that β-galactosidase is predictive of this benefit." The Examiner does not agree because the method used by Brooks et al. is directed to transducing different cell types from those recited in the instant claims, and further is directed to providing β-glucuronidase for the treatment of lysosomal storage disease, methodology not taught in the instant specification. Given the state of the art for gene therapy, undue experimentation, rather than routine experimentation was required to achieve the result reported by Brooks et al. Neither Brooks et al. nor the instant specification provides enabling guidance teaching one of skill in the art how to produce a therapeutic effect or prevent a CNS disorder by transducing cerebellar neurons using a lentiviral vector. Furthermore, given the state of the art of gene therapy, where constructs must be designed on a case by case basis and therapeutic protocols are developed by painstaking intensive research, the result reported by Brooks et al. would not be considered enabling by one skilled in the art for the treatment of all CNS disorders. The instant claims are directed to treating and preventing any central nervous system disorder and the specification refers to a wide variety of CNS disorders that will be treated or prevented using the claimed method. Thus, Applicants' arguments are not commensurate in scope with the scope of the claims.

The rejections are maintained for reasons of record.